Stratton VA Medical Center IRB Standard Operating Procedure

| TITLE: **Continuing Review of Research** | | | DOCUMENT NUMBER: **IRB-002** |
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| REVISION NO.: 01 | SUPERSEDES/DATE: 00/02-12-04 | EFFECTIVE DATE: May 14, 2004 | PAGE 1 OF 10 |

| IRB CHAIR OR DESIGNEE: | ACOS R&D: | COMPLIANCE: |
|---|---|---|
| Signature | Signature | Signature |
| Name: E. Fishman | Name: Donald Pasquale | Name: LESA PAULSEN CORTES |
| Date: 5/11/04 | Date: May-13-04 | Date: 5-14-04 |

## 1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, and federal regulations, and ICH Guidelines in the conduct of clinical research studies. Written procedures are required for documenting expedited and full committee continuing review of research, and to report the IRB's actions to the Principal Investigator(s).

## 2 DEFINITIONS

**Approval Date:** The date of the initial or most recent continuing approval of research as documented on correspondence to the Principal Investigator.

**Institutional Review Board (IRB):** The Stratton VA Medical Center Institutional Review Board, formally designated by Stratton VA Medical Center to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects.

**IRB Chair designee:** An IRB member with one or more years of experience on the IRB.

**IRB Staff:** Members of the Research Office who support the functions of the IRB.

**Principal Investigator(s):** Individual(s) who actually conducts a research investigation under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.

**Progress Report:** The completed progress report form and submitted attachments.

**Progress Report Deadline:** Approximately four weeks before the date of the IRB meeting at which continuing review is scheduled to occur. The progress report deadline may be extended to accommodate those reports received after the deadline if there is adequate time for review by the IRB staff and members.

## 3 FORMS

Non-Exempt Protocol Progress Report Form
Final Expedited Review Continuation Approval letter
Notification of Approval with Contingencies
Final Continuation Approval letter
Notification of Expiration
Notification of Disapproval letter
Exempt Protocol Progress Report

## 4 REFERENCE DOCUMENTS

45 CFR
21 CFR 50, 56
38 CFR 16
VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
ICH Harmonised Tripartite Guideline For Good Clinical Practice (1 May 1996)

## 5 PROCEDURE

5.1 Upon initial or continuing approval of research, the IRB grants an interval of approval appropriate to the degree of risk, but no longer than 365 days. The expiration date of the research (last day of interval of approval) is the date of the most recent initial or continuing approval plus the interval of approval. The date of the closest IRB meeting before the expiration date is the IRB meeting at which continuing review is scheduled to occur.

5.2 Approximately two months before the date of the IRB meeting at which continuing review is scheduled to occur, the IRB staff sends a Protocol Progress Report Form to the Principal Investigator.

5.2.1 The Principal Investigator is expected to complete the progress report form and provide all applicable attachments requested on the form.

5.2.1.1 The signature of the Principal Investigator(s) on the progress report ensures that all changes in previously approved research will be reported to the IRB. Proposed changes will not be implemented without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

5.3 Upon receipt of the progress report from the Principal Investigator(s), the Research Office stamps it with the date of receipt and enters the request into the database.

5.4 If the IRB does not receive an accurate and complete progress report by the submission deadline date, the Principal Investigator(s) will receive a Notification of Expiration and a copy will be sent to the Care Line Leader/supervisor and Pharmacy, if applicable.

5.5 The research becomes **unapproved** on the expiration date.

5.6 If an accurate and complete progress report is not received by the date indicated in the Notification of Expiration, the research will be suspended or terminated as determined by the IRB.

5.6.1 The Notification of Expiration will request verification that:

5.6.1.1 No subjects are currently enrolled in the research OR

5.6.1.2 Procedures are in place to minimize risks to current subjects when the research is suspended or terminated.

5.6.2 If the FDA regulates the research, the IRB Chair or designee will forward a copy of the IRB's decision to the FDA and the Research Compliance Officer within 10 business days of the decision.

5.6.3 If the FDA does not regulate the research, the IRB staff will notify the appropriate sponsor and the Research Compliance Officer within 10 business days of the decision.

5.6.4 The IRB Chair or designee will forward a copy of the IRB's decision to the Office of Research Oversight (ORO) within 10 business days of the decision.

5.6.4.1 A copy of the IRB decision will be placed in the research file.

5.7 Principal Investigators who are sent a Notification of Expiration become **ineligible** to submit new protocols until an accurate and complete progress report is received by the IRB and all other deficiencies are resolved.

5.7.1 New research submitted by ineligible Principal Investigators will not be reviewed.

5.7.2 Currently approved research is not affected by a Principal Investigator's ineligible status.

5.7.3 The list of ineligible Principal Investigators will be distributed to IRB members with the agenda and included with the meeting minutes.

5.7.4 Principal Investigators will be notified of their ineligible status in the Notification of Expiration.

5.8 The IRB staff checks the progress report for completeness and accuracy, and if applicable, compares it to the previous year's progress report.

5.8.1 Verify that the consent form, HIPAA authorization, and addendum consent, if applicable, of an active study are the most recently approved versions.

5.8.2 Verify that copies of all signed consent forms, HIPAA authorizations, and addendum consents, if applicable, have been sent to the Research Office within 5 days of enrollment.

5.8.3 Verify that the subject lists for current and previous progress reports are consistent with the approved number for total enrollment.

5.8.4 Verify that the progress report accounts for any serious adverse events of subjects at Stratton VA Medical Center and its affiliates for which the Research Office received written summaries.

5.8.5 Verify that the Research Office received written summaries for any serious adverse events mentioned in the progress report.

5.8.6 Verify that a current copy of the research grant, if applicable, or budget is in the file.

5.9 If any items are missing or questions have been answered unsatisfactorily, a member of the IRB staff will notify the Principal Investigator(s). The IRB staff will not process the paperwork until all corrections have been made.

5.9.1 The IRB and/or IRB staff can use sources other than the Principal Investigator(s) for verification of information in the progress report, such as Data Safety Monitoring Board reports, independent audits, or investigative subcommittees to determine that no material changes have occurred since the previous IRB review.

5.10 An IRB staff member reviews the progress report, and in consultation with the IRB Chair or designee, recommends whether the research qualifies for expedited review or requires full committee review.

5.11 Expedited Review Process:

5.11.1 A progress report qualifies for expedited review if any one of the following items are true:

5.11.1.1 The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for follow-up of subjects.

5.11.1.2 No subjects have ever been enrolled and no additional risks have been identified.

5.11.1.3 The remaining research activities are limited to data analysis.

5.11.1.4 The research originally qualified for review under expedited review and no additional risks have been identified.

5.11.2 A member of the IRB staff pre-reviews the research. The IRB Chair or designee conducts the review of:

5.11.2.1 The completed progress report form with current consent, HIPAA authorization, and/or addendum consent, if applicable.

5.11.2.2 Adverse event/safety reports/unanticipated problems involving risks to participants or others received during the reporting period.

5.11.2.3 Withdrawal of participants from the research or complaints about the research during the reporting period.

5.11.2.4 Summary of recent literature or findings.

5.11.2.5 Amendments or modifications received during the reporting period.

5.11.2.6 Relevant information about risks associated with the research or multicenter trial reports.

5.11.2.7 The current protocol including any modifications.

5.11.2.8 The updated Investigator Brochure, if applicable, received during the reporting period.

5.11.3 The IRB Chair or designee cannot have a conflict of interest with the research.

5.11.4 The IRB Chair or designee conducting expedited review has the final authority in deciding if continuing review of the research qualifies for expedited review and may recommend full committee review.

5.11.5 If the reviewer finds the research acceptable,

5.11.5.1 The IRB Chair or designee who reviewed the research approves the research.

5.11.5.2 The IRB Chair or designee signs and dates the Expedited Review Continuation Approval letter, indicating the risk level for this reporting period and the new interval of approval.

5.11.5.3 The IRB is notified of the approval in the agenda of the next scheduled IRB meeting.

5.11.5.4 The Expedited Review Continuation Approval letter is sent to the Principal Investigator(s).

5.11.6 The Date of Approval of research approved under expedited review is the date the IRB Chair or designee signs the approval.

5.12 Full Committee Review Process:

5.12.1 Progress reports that are recommended for full committee review are placed on the agenda of the monthly IRB meeting and are distributed approximately two weeks in advance of the meeting. The agenda identifies all IRB members who are also participating in the research to alert the committee to a conflict of interest.

5.12.2 All committee members are given a copy of the following items to review:

5.12.2.1 Completed progress report form with current consent form(s), HIPAA authorization, and addendum consent form, if applicable.

5.12.2.2 Adverse events/safety reports/unanticipated problems involving risks to participants or others received during the reporting period.

5.12.2.3 Withdrawal of participants from the research or complaints about the research during the reporting period.

5.12.2.4 Summary of recent literature or findings.

5.12.2.5 Amendments or modifications received during the reporting period.

5.12.2.6 Relevant information about risks associated with the research or multicenter trial reports.

5.12.3 The IRB staff assigns two primary reviewers, who are not participating in the research, based on their area of expertise.

5.12.4 Primary reviewers are given a copy of the current protocol, including any modifications to the protocol, and the updated Investigator Brochure received during the reporting period, if applicable. Information distributed to committee members is also given to the primary reviewers, as listed in 5.13.2.

5.12.4.1 Primary reviewers are provided with a primary reviewer form to record their comments.

5.12.5 The continuing review takes place at the monthly meeting of the IRB.

5.12.6 The IRB staff takes minutes at the IRB meeting pertaining to discussion of continuing review of research, and any controverted issues and their resolution.

5.12.7 Minutes are prepared within one week after the meeting and include the attendance of IRB members at the meeting, votes for, against, abstaining, recused, and excused, as well as the recommended period of approval, and if applicable, modifications or other changes to the research.

5.12.8 If the research is approved as submitted,

5.12.8.1 A Final Continuation Approval letter and a copy of the stamped consent(s) and HIPAA authorization, if applicable, are sent to the Principal Investigator(s).

5.12.9 If the research is approved with modifications,

5.12.9.1 A Notification of Approval with Contingencies, listing all required modifications and conditions for approval, is sent to the Principal Investigator(s).

5.12.9.2 The Principal Investigator(s) responds to the Research Office with a copy of all modified documents within 30 days.

5.12.9.3 The IRB staff reviews the modified documents for confirmation of all modifications required by the IRB.

5.12.9.4 If the submitted documents have not been modified as required, the Principal Investigator(s) is contacted by IRB staff and asked to submit the complete revision as requested.

5.12.9.5 Once the IRB staff determines that the documents contain all required modifications, the IRB Chair or designee signs the Final Continuation Approval letter. The letter and a copy of the stamped consent(s) and HIPAA authorization, if applicable, are sent to the Principal Investigator(s).

5.12.9.6 If the Principal Investigator(s) does not return the required modified documents within 30 days, the protocol will remain unapproved. At the next scheduled IRB meeting, the IRB will determine whether to suspend or terminate the research.

5.12.9.6.1 If the protocol approval period should expire before the modified documents are reviewed and approved by the IRB, the IRB Chair or designee will notify the Principal Investigator within 2 business days that no new participants may be enrolled until an approved consent form, HIPAA authorization, or addendum consent (if applicable) are stamped and approved.

5.12.9.7 If the research is suspended or terminated, a letter will be sent to the Principal Investigator and the Care Line Leader/supervisor within 2 business days, requesting verification that:

5.12.9.7.1 No subjects are currently enrolled in the research OR

5.12.9.7.2 Procedures are in place to minimize risks to current subjects when the research is suspended or terminated.

5.12.9.8 If the FDA regulates the research, the IRB Chair or designee will forward a copy of the letter to the FDA and the Research Compliance Officer within 10 business days of the decision.

5.12.9.9 If the FDA does not regulate the research, the IRB staff will notify the appropriate sponsor and the Research Compliance Officer within 10 business days of the decision.

5.12.9.10 The IRB Chair or designee will forward a copy of the letter to the Office of Research Oversight (ORO) within 10 business days of the decision.

5.12.9.10.1 A copy of the letter will be placed in the research file.

5.12.10 The Date of Approval for research approved by the full IRB is the date of the IRB meeting at which the research was approved.

5.12.11 The Date of Expiration is defined as the Date of Approval plus the interval of approval.

5.12.12 If the research is disapproved,

5.12.12.1 Consideration will be given to alternatives that will protect subjects currently enrolled in the research.

5.12.12.2 The IRB Chair will notify the Principal Investigator(s) in the Notification of Disapproval letter of the reasons for disapproval and will offer the Principal Investigator(s) an opportunity to respond in writing to the IRB by a given deadline.

5.12.12.3 If a written response is received by the deadline, the research and disapproval letter are reviewed at the next scheduled meeting of the IRB.

5.12.12.4 If a written response is not received by the deadline or the investigator does not contest the disapproval, the research remains unapproved. At the next scheduled IRB meeting, the IRB will determine whether to suspend or terminate the research.

5.12.12.5 If the research is suspended or terminated, a letter will be sent to the Principal Investigator and the Care Line Leader/supervisor within 2 business days, requesting verification that:

5.12.12.5.1 No subjects are currently enrolled in the research OR

5.12.12.5.2 Procedures are in place to minimize risks to current subjects when the research is suspended or terminated.

5.12.12.6 If the FDA regulates the research, the IRB Chair or designee will forward a copy of the letter to the FDA and the Research Compliance Officer within 10 business days of the decision.

5.12.12.7 If the FDA does not regulate the research, the IRB staff will notify the appropriate sponsor and the Research Compliance Officer within 10 business days of the decision.

5.12.12.8 The IRB Chair or designee will forward a copy of the letter to the Office of Research Oversight (ORO) within 10 business days of the decision.

5.12.12.8.1 A copy of the letter will be placed in the research file.

5.13 Consents, HIPAA authorization, and assents associated with approved research will be stamped with a Date of Approval and a Date of Expiration. A copy of the stamped consent(s), HIPAA authorization, assent, if applicable, and approval letter, indicating the risk level for the reporting period and the new interval of approval, will be provided to the Principal Investigator(s).

5.14 Copies of all research documents received and sent are filed in the Research Office.